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Preliminary Evaluation of Sesbania Seed Gum Mucilage as Gelling Agent

Gayatri C. Patel[*1], Madhabhai M. Patel[2]

[1*]Department of Pharmaceutics, Maliba Pharmacy College., Surat- 394350, Gujarat, India.

[2]Principal, Kalol Institute of Pharmacy, Kalol, Gujarat, (India).

[*]E-mail: gayatripatel26@gmail.com

[*]Phone no. : (02625) 255144,255882,[*]Fax no. : (02625) 255882

ABSTRACT: The mucilage from the endosperm of Sesbania grandiflora seeds (Family Leguminosae) was extracted by multiple maceration technique using water as solvent that, yield a high proportions of (33%) of mucilage. Such mucilage when mixed with water, a protective and soothing preparation results. The objective of the present work is to study the Sesbania gum mucilage as gelling agent. To study the gelling properties, gels were prepared using Diclofenac diethyl ammonium (DD) as model drug. Six batches of drug loaded gels with concentration of mucilage corresponding to 2.0,2.25,2.5,2.75,3.0 and 3.5%w/w were formulated by using glycerin as wetting agent and thiomersol as preservative. The prepared gels were evaluated for DD content, pH, rheological studies such as viscosity and extrudability, in vitro diffusion profile and stability studies. The gel prepared with 2.5% of Sesbania gum mucilage showed desired gel characteristics with better drug release profile when compared with marketed formulation. Stability study revealed that the gel formulations were physically stable and has no syneresis.

Key words: Sesbania gum mucilage, Diclofenac diethylammonium (DD), Spreadibility

INTRODUCTION

In recent years, plant gums have evoked tremendous interest due to their diverse pharmaceutical applications such as diluent, binder, disintegrant in tablets, thickeners in oral liquids, protective colloids in suspensions, gelling agents in gels and bases in suppository[1]. The gums are biocompatible, cheap and easily available. Thus making them attractive substitutes for costly semi synthetic and synthetic excipients[1].

Sesbania seed gum (SG) is available locally and has not been explored as pharmaceutical excipients. The SG was obtained from the endosperms of the seeds of Sesbania grandiflora (Family Leguminosae) yield a high proportion of (33%) of mucilage. It contains high molecular weight hydrocolloidal polysaccharides composed of galactan and mannan units combined through glycosidic linkages very much similar to that obtained from guar gum having D-galactose –D mannose ratio of 1:2[2]. It has been used as a substitute for gum arabic in some applications[3,4].

Many plants contain mucilages, which provide high concentration of complex sugars. When this mucilage are mixed with water, a protective and soothing preparation results, which can be applied externally. Hence, the main aim of present work was to evaluate the suitability of Sesbania gum mucilage as a gelling agent in topical formulation. Diclofenac Diethylammonium used as modal substrate.

EXPERIMENTAL

Materials

The materials used were Diclofenac diethylammonium (DD) was obtained as gift sample from Welable Pharmaceutical Ltd., Mehsana, and Sesbania seed powder was obtained from Vinayak Gum Industries, Ahmedabad. All other chemicals and reagents were of analytical grade. Deionized distilled water was used throughout the experiment.

Modification of SG

In the present work native SG was collected and the sample was modified as follows:

SG was suspended in 9:1 acetone: chloroform mixture for 6 hr with intermittent stirring and supernatant which contain extraneous impurities (organic solvent soluble impurities) was removed. The precipitated gum was filtered, washed two times with organic mixture and dried

in a hot air oven at 45°C. The dried powder was passed through a 150 # sieve and used for further investigations.

Determination of gel forming concentration of mucilage

Gel forming concentration of Sesbania gum mucilage was determined by mixing the required quantity of gum with distilled water by using laboratory stirrer (Model no RR-121/D, Remi stirrer, India) and allowed to stand for 1 hr, so as to enable the gum to swell. Thus, base on consistency gelling concentrations of Sesbania gum mucilage were found out.

Preparation of gels

Six batches of gels were prepared corresponding to 2.0,2.25,2.5,2.75,3.0 and 3.5%w/w Sesbania gum mucilage, DD (1%w/w) as modal drug, glycerin (10%v/w) as wetting agent and thiomerosal (0.01%) as preservative. First the weighed amount of gum mucilage was wetted by glycerin and half of the quantity of water was then added. The dispersion was allowed to keep in room temperature for 1 hr to obtain the hydrate viscous mixture. The DD and thiomerosal were dissolved in the rest of water and dispersed slowly to the gel formulations by mixing gently to obtain homogenous gel at room temperature. The gels were obtained after final weight adjusted with water to 100 g and allowed to stand for complete hydration at room temperature for 24 hrs and stored in cool place prior to its use. The composition of gels is mentioned in Table1.

Evaluation parameters

The prepared gel were evaluated for parameters such as DD content, pH measurements, Rheological studies such as viscosity and extrudability, in vitro diffusion profile and stability studies.

Drug content studies[5]

DD gels (0.5g) were weighed and diluted with about 50 ml of pH 7.2-phosphate buffer in a volumetric flask and appropriate dilutions were made with the same buffer solution. The resulting solution was then filtered using 0.45-μm cellulose acetate membrane filters and the amount of DD was determined at 276 nm using UV-spectrophotometer (Systronic 2201, Japan). The observations are shown in Table 2.

Measurements of pH

The pH was measured in each gel, using a digital pH meter (Systronic, 361-micro pH meter), which was calibrated before use. The measurements of pH of each data were in triplicate and the average values are given in Table 2.

Rheological studies

Viscosity

A Brookfield digital viscometer Helipath (Model no LVDV 2P230) with spindle no and speed was used to measure the viscosity in cps of the suspensions. The sample temperature was controlled at 25±1°c before the each measurements. The results are given in Table 2.

Extrudability[6]

A simple method was adopted for determination of extrudability in terms of weight in grams required to extrude a 0.5 cm ribbon of gel in 10 sec from the collapsible tube. The results are given in Table 2.

In vitro diffusion profile[5]

In vitro diffusion profile of the gel was determined by using Franz diffusion cells. A piece of 0.8 μm polymeric membrane with 2.2 cm^2diffusion area was used as a barrier. The diffusion studies were carried out at 37±0.5 c using pH 7.2 phosphate buffer as (receptor phase) diffusion medium. One gram of the gel of each formulation was exposed to diffusion study and samples were withdrawn at different time intervals such as 0.5,1,2,3,4,5,6 and 8 h with additive of appropriate amount of same fresh buffer solution to keep the volume constant. The samples were analyzed by UV spectrophotometer (Systronic 2201, Japan) at 276 nm. Cumulative percentage drug release at different time intervals was calculated using the regression equation generated from the standard curve. (Table 2 and Figure 1). Each data point represented the average of three determinations. In vitro release studies were observed for an eight-hour period.

Market sample of gel was also tested for dissolution profiles and compared with that of prepared gels.

Data analysis: The cumulative amount of DD was plotted against time and the slope of the linear portion of the curve estimated by zero order, first order and higuchi ($Q\sqrt{t}$) kinetics (Table 3).

Stability studies[7]

Prepared gels were stored in glass containers (well stoppered) for three months in the dark at room temperature (25±1°C). They were checked after preparation and monthly throughout three-month period. Physical evaluation of stability of the prepared gel formulation was carried out by visual inspection and rheological tests.

RESULTS AND DISCUSSION

The gelling concentration of the Sesbania gum mucilage was varied between 2 - 3.5% and this concentration was completely dissolved in the gel. Hence, six batches of gels were prepared corresponding to 2.0, 2.25, 2.5, 2.75, 3.0 and 3.5% w/v of Sesbania gum mucilage, DS (1%) and glycerin (10%v/w) as wetting agent. The microbial load of mucilage was measured and found to be 98 CFU/gram of mucilage and hence 0.01% thiomersol was added as preservative.

All gel formulations were clear, smooth, pliable, homogenous and elegant in appearance when applied on the skin with the finger. The pH of all the formulations was determined and these were no significant difference in pH (~7), which was ideal for topical preparation. Among the formulated gels, the batch containing 2.5%

mucilage had good spreadibility and desired gel characteristics with pH of 7.2 were observed. Therefore, this was considered as ideal batch.

In vitro diffusion profile: The cumulative amount of DS release from the gels containing different concentration of Sesbania gum mucilage after 8 hr are shown in Table 2 and profiles are shown in figure-1. All the gels showed differences in their drug release. In general, drug release times were a function of Sesbania gum mucilage in the gels. From the figure, it is observed that the drug diffusion profile from the prepared gels follow zero order and higuchi kinetics rather than first order. It was observed that in gels composed of 2.5% of Sesbania gum mucilage showed 80% drug release over a period of 8h. This batch was identical to that of marketed formulation. Stability study revealed that the gel formulations were physically stable and has no syneresis.

CONCLUSION

From the present preliminary studies, it could be concluded that Sesbania gum mucilage can be used as gelling agent for the development of gel formulations, because of its good release profile, water-soluble nature, physical stability and good spreadibility. Further studies will be worthy to establish the mucilage as potent gelling agent.

Table 1: Compositions of DD Gel (Batch coded)

Ingredients	Batch code					
	F1	F2	F3	F4	F5	F6
SG	2.0	2.25	2.5	2.75	3.0	3.5
DD	1.16	1.16	1.16	1.16	1.16	1.16
TMS	0.01	0.01	0.01	0.01	0.01	0.01
Glycerin	10	10	10	10	10	10
Distilled water *	100	100	100	100	100	100

Note: 1) All the quantity in terms of %w/w.
2) * Quantity sufficient to make 100 gm.
3) SG-Sesbania Gum, DD -Diclofenac diethylammonium, TMS- Thiomerosal.

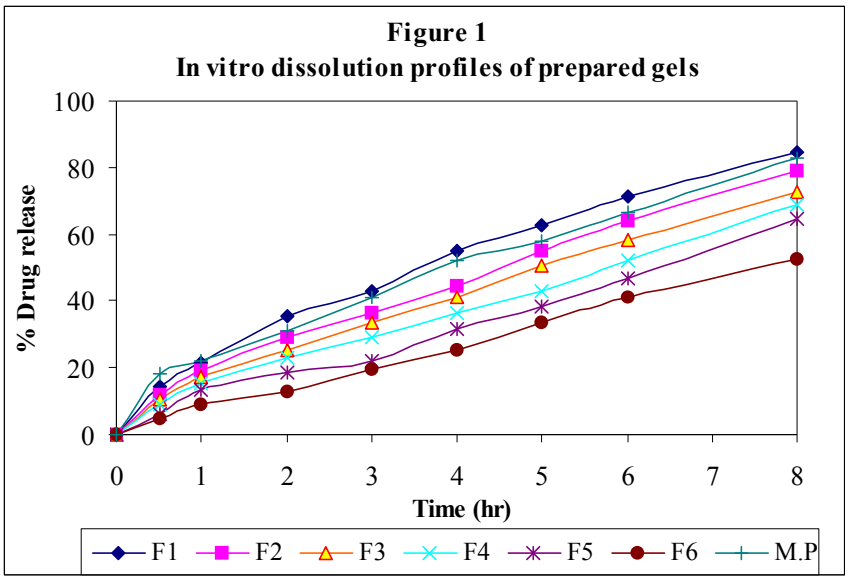
Table 2 : Physical characteristics of gels

Batch Code	Drug content (DD%)±S.D.	pH	Viscosity (cps)±S.D.	Extrudibility	Amount of drug release after 8 h (%)±S.D.
F1	94.66±0.4979	6.90	1052±4.50	+	78.35±0.398
F2	96.75±0.6123	7.25	1314±5.37	+ +	74.12±0.452
F3	97.50±0.5129	7.29	1515±6.20	+ + +	80.55±0.548
F4	94.61±0.4403	7.32	1696±8.90	+ +	71.50±0.362
F5	95.22±0.6141	7.36	1980±4.25	+	66.45±0.545
F6	95.66±0.3536	7.42	2230±7.39	+	59.50±0.499
MP	98.02±0.457	7.15	1425±3.60	+ + +	81.45±0.436

Note: 1) +: good; + +: very good; + + +: excellent.
2) All measurements were made in triplicate.
3) M.P-Market product

Table 3: Kinetics Parameters Calculated From In Vitro Diffusion Profile Data

Batch code	Zero order kinetic	Q√t kinetic	First order kinetic
	R^2	R^2	R^2
F1	0.9668	0.9943	0.8447
F2	0.9844	0.9871	0.8810
F3	0.9971	0.9832	0.9040
F4	0.9909	0.9785	0.8901
F5	0.9912	0.9615	0.8861
F6	0.9957	0.9530	0.8999
M.P	0.9815	0.9750	0.8865



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